DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 20, 2015

L&K Biomed Company, Limited
Ms. Yerim An
#201, 202 16-25, Dongbaekjungang-ro 16 beon-gil
Giheung-gu, Yongin-si
Gyeonggi-do, 446-916
Republic of Korea

Re: K143279
Trade/Device Name: LnK Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: February 13, 2015
Received: February 18, 2015

Dear Ms. An:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143279

Device Name
LnK Anterior Cervical Plate System

Indications for Use *(Describe)*
The LnK Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine (C2-C7). The System is indicated for use in the immobilization and stabilization of the spine as an adjunct to fusions in patients with:

- degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
- spondylolisthesis,
- trauma (i.e. fractures or dislocations),
- tumors,
- deformity (defined as kyphosis, lordosis, or scoliosis),
- pseudoarthrosis,
- failed previous fusion,
- spinal stenosis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

The following 510(k) summary is being submitted as required by 21 CFR 807.92(a):

1. Submitter:

L&K BIOMED Co., Ltd.
#201, 202 16-25, Dongbaekjungang-ro 16 beon-gil
Giheung-gu, Yongin-si, Gyeonggi-do, 446-916,
Korea
Phone. 82-70-7600-6064
FAX .82-70-7813-3355

Contact Person: Yerim An

Date prepared: February 13, 2015

2. Device Identification

Trade Name	LnK Anterior Cervical Plate System
Common Name	Anterior Cervical Plate
Product Code	KWQ
Classification Name	Spinal Intervertebral Body Fixation Orthosis (21 CFR 888.3060)

3. Predicate or legally marketed devices which are substantially equivalent

- **L&K Biomed:** LnK Anterior Cervical Plate System (K113509) **(Primary)**

4. Description of the Device

The LnK Anterior Cervical Plate System is composed of plates and screws which are made from titanium alloy Ti-6Al-4V ELI (ASTM F136). These plates attach to the anterior cervical spine with a minimum of four screws per plate. The plates are offered in one-level, two-level, three-level and four-level fusion configurations (13~97mm). The plate screws are 3.5mm and 4.0mm diameter head screws. They are self-tapping and self-drilling threaded. All implants are provided non-sterile.

5. Intended use

The LnK Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine (C2-C7). The System is indicated for use in the immobilization and stabilization of the spine as an adjunct to fusions in patients with:

- degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
- spondylolisthesis,
- trauma (i.e. fractures or dislocations),
- tumors,
- deformity (defined as kyphosis, lordosis, or scoliosis),
- pseudoarthrosis,
- failed previous fusion,
- spinal stenosis.

6. Comparison of the technology characteristics of the device to predicate and legally marketed devices

There are no significant differences between the additional size of LnK Anterior Cervical Plate System and other systems currently being marketed. It is substantially equivalent to these other devices in design, function and intended use.

7. Performance Data

Static compression bending, tension, torsion and dynamic compression bending were performed according to ASTM F1717 on a worst-case, cervical plate construct. These data demonstrate substantial equivalence in terms of performance bench testing.

8. Conclusion

The additional size of Anterior Cervical Plate System is substantially equivalent to the devices referenced above and is therefore safe and effective for its intended use.